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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/627,531	07/28/2000	Stephen A. Berry	ARC2914C1	3299

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EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 05/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/627,531

Applicant(s)

BERRY ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-27, 29-31, 33-41 and 49-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-27, 29-31, 33-41 and 49-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/05/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, change of Power of Attorney, substitute specification, IDS and amendment and remarks, al filed 11/06/03. Claims 17-27, 29-31, 33-41 and 49-53 are pending.

Claim Rejections - 35 USC § 112

The rejection of claims 50 and 51 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of amendments to claims 17, 50 and 51.

However, claims 33-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The invention appears to be directed to non-aqueous, single-phase vehicle. Claims 33-35 recite suspension. Suspensions are not single-phase formulations. Explanation is required

1. Applicants' arguments with respect to claims 17-27, 29-31, 33-38-41, 49,52 and 53 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 17-19, 24-31, 36, 52 and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Daher et al. (US 4,376,118).

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Daher discloses a non-aqueous solution that comprises a mixture of tetracycline antibiotic salt, non-aqueous diluent, non-aqueous solvent, non-aqueous non-ionic solubilizer, antioxidant and non-aqueous anionic solubilizer (abstract). Lauryl lactate is a diluent (column 1, line 58), polysorbates, ethylene oxidepropylene oxide block copolymers are non-aqueous solubilizers (column 2, lines 6-12), and ethanol or methanol or N-methyl-pyrrolidone are solvents (column 1, lines 51-53). The route of administration of a composition carries no patentable weight and instant formulation is adapted for implantation in instant claim 27. The instant method claims administers the instant generic composition and the antibiotic composition of the prior art is expected to be administered to a subject in need thereof. Daher meets the limitations of the claims.

Claim Rejections - 35 USC § 103

4. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daher et al. (US 4,378,118).

Daher discloses the non-aqueous single-phase composition of the instant claims. Daher does not teach the amounts of the active agents recited in claims 20 and 21. However, there is no demonstration in applicants' specification showing that the recited amounts of active or beneficial agent provides unusual results and the person of ordinary skill in the art is able to incorporate an amount of tetracycline desired to produce the desired effect in a subject thereof. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare and administer the tetracycline formulation of Daher. One having ordinary skill in the art would have been motivated to incorporate specific amounts of tetracycline with the expectation of producing the desired effect.

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5. Claims 40, 41 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daher et al. (US 4,376,118).

Daher discloses the instant formulation but fails to teach the ratios recited for the solvent, surfactant and polymer. Regarding administering the composition/formulation daily to a subject, it is within the purview of the ordinary or skilled artisan determine the duration of the treatment for effective management of the condition being treated and tetracycline can be delivered by implantation as disclosed by the teaching reference, Jernberg, US 5,290,271. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the non-aqueous solution of Daher. One having ordinary skill in the art would have been motivated to use appropriate amounts of solvent, surfactant and polymer with the expectation of producing non-aqueous vehicle.

6. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Daher et al. (US 4,376,118) in view of Jernberg (US 5,290,271).

Daher discloses administering the instant formulation. Daher does not disclose administration by implantation. But is known that tetracycline can be administered by implantation (see column 4, line 21 and abstract). Jernberg is thus relied upon for administering tetracycline by implantation. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to administer the tetracycline composition of Daher. One having ordinary skill in the art would have been motivated to administer the composition of Daher by implanting the tetracycline formulation with the expectation of delivering the antibiotic to the site needing treatment.

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7. Claims 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daher et al. (US 4,376,118) in view of GB 1,049,104.

Daher discloses the formulation and administration of the tetracycline to a subject in need thereof. It is within the purview of the ordinary or skilled artisan to administer the tetracycline formulation of Daher for a specific period of time that is long enough to treat the condition. Daher does not disclose parenteral administration of the tetracycline formulation. However, it is known that tetracycline can be parenterally administered (page 1, lines 70 and 71 of GB 1,049,104). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to administer the formulation of Daher. One having ordinary skill in the art would have been motivated to parenterally administer Daher's formulation with the expectation of effective delivery and treatment.

8. Claims 50 and 51 rejected under 35 U.S.C. 103(a) as being unpatentable over Daher et al. (US 4,376,118) in view of Bergy et al. (US 3,632,768).

Daher discloses the instant formulation. Daher does not a tetracycline formulation where the polymer is polyvinylpyrrolidone. Regarding claim 51 where glycerol monolaurate is the surfactant instead of the polysorbate recited in claim 50, one surfactant can be substituted for another without changing the characteristic of the composition. As a teaching reference, Bogdansky discloses a composition that can contain tetracycline, polyvinylpyrrolidone and glycerol monolaurate (column 4, line 47; column 5, lines 31, 32 and column 3, line 50 to column 6 line 11). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the tetracycline formulation of Daher. One having ordinary skill in the art would have been motivated to substitute block copolymer of Daher with

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polyvinylpyrrolidone of Bogdansky with the expectation that the effectiveness of tetracycline as an antibiotic is not affected.

9. Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daher et al. (US 4,376,118) in view of Bogdansky et al. (US 5,284,655).


Daher discloses a tetracycline formulation. The formulation of Daher does not contain protein. However, Bogdansky discloses composition comprising autogenous or alogenic bone particles, polyvinylpyrrolidone (polymer), glycerol monolaurate and tetracycline or protein (column 4, line 47; column 5, lines 31, 32 and column 3, line 50 to column 6 line 11). Protein and tetracycline are equivalent as active agents in Bogdansky. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the tetracycline formulation of Daher. One having ordinary skill in the art would have been motivated to substitute protein for tetracycline with the expectation that the protein containing formulation will be flowable and suitable for implantation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 242-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Blessing Fubara
Patent Examiner
Tech. Center 1600